REMARKS

Applicants have reviewed the Office Action mailed on February 23, 2006 and offer the following remarks. Claims 17-30 are under consideration. Amendments to the Specification address objections made by the Examiner. No new matter has been added.

Objections to the Specification

The Examiner has objected to the disclosure as it contains an embedded hyperlink. Applicants have removed all hyperlinks from the specification.

Claim Rejections

35 U.S.C. § 101

Claims 17 to 30 were rejected under 35 U.S.C. § 101 as being drawn to an invention with no apparent or disclosed specific and substantial credible utility. The Examiner argues that the putative transporter protein of the instant invention and antibodies that bind specifically thereto lack a specific and substantial utility because the instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process which one would wish to diagnose, measure or manipulate for a desired clinical effect or to diagnose or treat by employing antibodies. The instant polypeptide is identified as an orphan transporter where the identity of the physiological processes moderated by it are not known. Absent this, antibodies against the protein have neither a specific or substantial utility. The instant specification does not disclose a credible, specific and substantial "real world" use for applicant's protein and the protein is of undetermined functional and biological significance. Until some actual and specific significance can be attributed to the putative transporter protein of the instant

invention, the Examiner concludes the claimed invention is incomplete and does not meet the requirements of 35 U.S.C. § 101 as being useful.

Additionally, the Examiner compares the application to Brenner vs. Manson such that employing the instant protein in the identification of activity modulating compounds without being able to predict what clinical effects of those compounds will have based upon their modulatory activity is to employ that protein as the object of further research.

35 U.S.C. § 112

Claims 17 to 30 were rejected under 35 U.S.C. § 112, 1st paragraph, for failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

Applicants respectfully disagree. Applicants have identified the instant protein of SEQ ID NO: 2 as a mitochondrial solute carrier.

As stated in the specification on page 13, this protein belongs to the mitochondrial solute carrier family and the peroxisomal calcium-dependent solute carrier subfamily, is found at the mitochondrial inner membrane, and functions in the transport of metabolites across the membrane. Zellweger syndrome and X-linked adrenoleukodystrophy are human metabolic diseases associated with the mitochondrial solute carrier family (Weber et al., p. 8509, column 2, 2nd paragraph, Ref. V cited by Examiner and cited in the IDS filed 11/3/2003). The mitochondrial solute carrier of SEQ ID NO: 2 therefore has a disclosed specific and substantial credible utility, as would the antibodies that selectively bind it.

Applicants conclusion that a disclosed specific and substantial credible utility is provided for the mitochondrial solute carrier of SEQ ID NO: 2 is additionally supported by del Arco et al. (J. Biol. Chem., Vol. 279, pp. 24701-24713, June, 2004). Del Arco et al. characterize a protein that differs from the instant SEQ ID NO: 2 by only one conservative amino acid substitution ($Ala_9 \rightarrow Val_9$) as a mitochondrial carrier protein that transports metabolites across the mitochondrial inner membrane. Therefore, a disclosed specific and substantial credible utility has been provided.

The U.S. Patent and Trademark Office Utility Guidelines set forth the utility requirement that a claimed invention must have a specific, substantial and credible utility. These requirements are defined in broad terms in cases such as *Brenner v. Manson*, 148 USPQ 689 (S. Ct. 1966) and in the recently adopted Utility Guidelines from the USPTO.

The Examiner stated that the present invention failed to disclose any properties of the present invention, SEQ ID NO: 2 that associated with any disease state or disorder. However, such a requirement substantially conflicts with the decision made by the CCPA.

The CCPA in *Nelson v. Bowler*, 206 USPQ 881 (CCPA 1980), clearly accepted a showing of less than a specific therapeutic use of a claimed chemical compound as satisfying the utility requirement.

> *The CCPA held that where a claim does not provide evidence of pharmacological activity of a claimed compound, although it does not establish a specific therapeutic use, manifests a practical utility because knowledge of pharmacological activity is beneficial to the public in that it makes faster and easier for medical researchers to combat illnesses. Nelson v. Bowler, 206 USPQ 881 (CCPA 1980).*

The notion that a recognized valuable addition to even entry points of the drug discovery cycle advances the art sufficient to establish a "usefulness" of a claimed invention should not be ignored. Similar to the *Nelson* case, the present invention, which is drawn to antibodies against a mitochondrial solute carrier, has useful value in the drug discovery process. According to *Nelson*, the present invention provides sufficient knowledge and information that is beneficial to the public, and provides sufficient guidance for researchers to use the claimed subject matter to develop disease treatments and/or diagnostics. It recognized that the mitochondrial solute carrier is a target for pharmacological action (p. 13, lines 22-25). The public disclosure of a new member of this family through the patenting process clearly advances the art and augments the capabilities of biomedical researchers to combat illnesses.

With regard to lack of a well-established utility, Applicants respectfully believe that this is not relevant to the instant invention as a specific and substantial utility has been disclosed in the instant specification and the credibility of this utility has not been

questioned. No art has been provided to suggest that the instant polypeptide is not a mitochondrial solute carrier, as disclosed in the specification.

The utility rejection raised by the Examiner also conflicts with the case *Juicy Whip v. Orange Bang* (Fed. Cir. 1999). *Juicy Whip* held that, in order to violate the utility requirement, an invention must be "totally incapable of achieving a useful result." The antibodies and polypeptide molecules of the present invention are well known in the art to be valuable as drugs and drug targets and therefore have readily apparent commercial utilities, such as for screening potential drug compounds, producing antibodies, etc. Therefore, the present invention is not "totally incapable of achieving a useful result." Instead, it is useful.

The applicants assert that one of skill in the art would be able to practice the claimed invention based upon the sequences and disclosure of the present specification and thus the invention is enabled. The claimed invention is supported by both specific and substantial utilities and, consequently, one of ordinary skill in the art would know how to use the claimed invention. Therefore, applicants respectfully request that the Examiner withdraw the rejection.

35 U.S.C. § 112

Claims 18, 20, 22, 24, 26, 28 and 30 were rejected under 35 U.S.C. § 112, 1st paragraph. The Examiner contends that as the claims are directed to antibodies against a protein that "comprises SEQ ID NO: 2," the instant specification does not provide a written description or the guidance needed to produce an antibody which binds to any epitope other than an epitope which is contained within SEQ ID NO:2 of the instant application. This is due to the fact that epitopes are no more than 6 to 8 amino acids in length and that fusion proteins comprising a recombinant protein and an antigenic tail are well known in the art. The instant claims essentially encompass any antibody which can bind to any polypeptide or protein.

Applicants respectfully disagree. As indeed antigenic fusion-protein components are well known, antibodies against these antigens (FLAG epitope, Protein A, etc.) fused to a protein would not be encompassed by the scope of the instant claims as the claims are directed to an antibody "that selectively binds to a polypeptide, wherein the amino

acid sequence of said polypeptide comprises SEQ ID NO:2..." Antibodies that bind to antigens fused to a protein of interest would not be selectively binding to a protein comprising SEQ ID NO:2. Such antibodies would bind any fusion protein comprising any protein sequence fused to those specific antigenic determinants recognized by those antibodies. As defined in the specification on page 34, lines 22-23, an antibody "selectively binds" a target peptide when it binds the target peptide and does not significantly bind to unrelated proteins. Based upon the "selectively binds" language of the claims, antibodies which are designed to bind antigens such as FLAG epitope, Protein A, etc. as part of a fusion protein would be clearly outside the scope of the claims. Applicants therefore request withdrawal of this rejection.

35 U.S.C. § 102

Claims 18, 20, 22, 24, 26, 28 and 30 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hopp et al. (US 5,011,912). The Examiner states that the claims encompass an antibody which binds to any antigenic peptide, including the FLAG epitope bound by the antibody of Hopp et al.

Applicants respectfully disagree. As Hopp et al. does not even disclose the instant polypeptide comprising SEQ ID NO: 2, the antibodies of Hopp et al. would not be able to selectively bind a protein comprising SEQ ID NO: 2. As defined in the specification on page 34, lines 22-23, an antibody "selectively binds" a target peptide when it binds the target peptide and does not significantly bind to unrelated proteins. Based upon the "selectively binds" language of the claims, antibodies which are specifically designed to bind peptides used for immunologically tagging recombinantly expressed proteins, such as the antibody that binds a FLAG peptide as described by Hopp et al., are not within the scope of the instant claims and therefore Hopp et al. would not be an anticipatory reference. Applicants therefore request withdrawal of this rejection.

Claims 17, 18, 21, 22, 25 and 26, were rejected under 35 U.S.C. § 102(b) as being anticipated by Weber et al. The Examiner states that the amino acid sequence of the solute

carrier protein of Weber et al. is greater than 95% identical to the amino acid sequence of SEQ ID NO:2 and that Weber et al. describe labeled polyclonal antibodies that are encompassed by the instant claims.

Applicants respectfully disagree. While Weber et al. disclose antibodies against a protein that is greater than 95% identical to the amino acid sequence of SEQ ID NO:2, the two proteins are not completely identical in sequence. With variations in the amino acid sequence between the two proteins, these two proteins have different epitopes present and would generate different antibodies. An antibody that binds the instant SEQ ID NO: 2 would not necessarily bind the protein taught by Weber et al. and vice versa. Claims 17, 18, 21, 22, 25 and 26 are directed towards an antibody that selectively binds to a polypeptide of SEQ ID NO: 2, which is not the same protein as that of Weber et al. Therefore the instant claims are not anticipated by Weber et al. and the rejection should be withdrawn.

35 U.S.C. § 103

Claims 17-30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over either of the Hopp et al. or Weber et al., each in view of Maurer et al. publication.

Applicants respectfully disagree. Neither Hopp et al., Weber et al., or Maurer et al., alone or in combination, teach the invention of claims 17-30. Neither of the references corrects the deficiencies of the other. As Hopp et al. does not even disclose the instant polypeptide comprising SEQ ID NO: 2, the antibodies of Hopp et al. would not be able to selectively bind a protein comprising SEQ ID NO: 2. While Weber et al. disclose antibodies against a protein that is greater than 95% identical to the amino acid sequence of SEQ ID NO:2, the two proteins are not completely identical in sequence. As explained supra, with variations in the amino acid sequence between the two proteins, these two proteins have different epitopes present and would generate different antibodies. An antibody that binds the instant SEQ ID NO: 2 would not necessarily bind the protein taught by Weber et al. and vice versa. Claims 17-30 are directed towards an antibody that selectively binds to a polypeptide

of SEQ ID NO: 2, which is not the same protein as that of Weber et al. Maurer et al. reviews aspects of producing antibodies. Maurer el al. does not teach a polypeptide of SEQ ID NO:2 nor antibodies against the polypeptide of SEQ ID NO:2.

Neither of the references, alone or in combination, teach the protein of SEQ ID NO: 2 or antibodies that selectively bind SEQ ID NO:2. Neither of the references corrects the deficiencies of the other references or provides any teaching on how to address these deficiencies. Therefore claims 17-30 would not have been *prima facie* obvious to one of ordinary skill in the art in view of Hopp et al., Weber et al. and Maurer et al. The rejection of the instant claims should therefore be withdrawn.

CONCLUSION

Claims 17-30 are pending. By way of the above amendments and arguments, Applicants have addressed all the objections and rejections raised by the Examiner. Applicants believe that the present application is now in condition for allowance.

The Examiner is invited to contact the undersigned in order to advance prosecution.

Respectfully submitted,
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